UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel. JOHN A. WOOD, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, Plaintiffs, v. ALLERGAN, INC. and ALLERGAN plc, Defendants.	Civil Action No. 10 Civ. 5645 (JMF) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' REPLY BRIEF
IN SUPPORT OF THEIR MOTION TO DISMISS
RELATOR'S THIRD AMENDED COMPLAINT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Regulations

Other Authorities

INTRODUCTION

This Court offered Plaintiff-Relator John A. Wood ("Relator") an opportunity to replead once more—but only once more, ECF 72—to remedy the deficiencies that Defendants identified in their Motion to Dismiss, *see* ECF 64, 65.[1] Instead of repleading, Relator filed an Opposition, ECF 73, that ducks many of Allergan's legal arguments—and resorts to reimagining his TAC's allegations in an effort to respond to the remainder. Nothing in the Opposition or the U.S. Government's Statement of Interest, ECF 78, rescues Relator's legally deficient pleading.

No Remuneration. As the Opposition reinforces, Relator's TAC fails to plead a violation of any applicable anti-kickback statute.[2] Relator's Opposition all but ignores the text of the Prescription Drug Marketing Act ("PDMA"), 21 U.S.C. § 353 *et seq.*, which permits pharmaceutical companies to provide samples to increase prescriptions. The Opposition also offers no viable counter to U.S. Department of Health and Human Services, Office of Inspector General ("OIG") guidance that samples are worthless to physicians (absent some allegation that physicians sold or billed for the samples). OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance"), 68 Fed. Reg. 23,731, 23,739 (May 5, 2003). Relator fares no better with his arguments regarding the value to physicians of the other purported inducements (e.g., the patient care kits) because he never squarely responds to Allergan's argument that his theory is implausible in light of his own TAC's allegations.

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[1] The operative pleading is Relator's Third Amended Complaint ("TAC"). ECF 38. As the Opposition noted, Defendants and Relator executed a dismissal and tolling agreement as to Allergan plc. After the Government consents, Relator will file a notice of dismissal under Rule 41(a)(1)(A)(ii). In the meantime, Allergan plc joins Allergan, Inc. in the arguments herein. This reply does not waive any further personal jurisdiction arguments that Allergan plc might make if the Government or the Court does not approve the voluntary dismissal.

[2] As Relator has not distinguished between federal and state false claims acts and anti-kickback statutes, the same arguments that require dismissal of his federal counts also require dismissal of his state counts. Similarly, Relator's sparse, conclusory "conspiracy" allegations, *see* ECF 38 ¶¶ 282–284, fail in light of the insufficiency of Relator's substantive FCA allegations. *See, e.g.*, *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 50 (2d Cir. 2016) (the FCA's conspiracy provision is "merely derivative" of the substantive provisions).

No Falsity. Even if Relator had alleged a tenable AKS violation—and he has not—he would still have to plead plausibly that the violation rendered claims false for purposes of the FCA.[3] This the TAC fails to do. Even before *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), divisions of this Court had rejected Relator's theory that AKS violations "taint" resulting claims for reimbursement. By embracing common-law fraud principles in *Escobar*, the Supreme Court confirmed that Relator cannot slide by without identifying a false or fraudulent claim or false statement or misleading omission. Although Relator and the Government proffer several types of "false" statements (allegedly made by unspecified physicians or pharmacies), those statements are either forward-looking or personal to the speaker (or both). Thus, those statements are not false, fraudulent, or materially misleading.

No Particularity. Relator's Opposition concedes that the TAC does not satisfy this Court's Rule 9(b) particularity standard, which requires an FCA plaintiff to plead "representative examples" of the allegedly false claims. Relator proposes a lesser standard, but his TAC falls short of that mark as well, because his allegations do not include, *inter alia*, the identity of any physician or pharmacy that allegedly made a false statement or the details of any prescription that purportedly resulted from Allergan's alleged misconduct.

Multiple Procedural Defects. Lastly, Relator's Opposition fails to explain away the TAC's procedural flaws and state law infirmities. As the Opposition confirms, Relator filed his TAC while two other materially identical FCA suits were pending; thus, the FCA's first-to-file and public disclosure provisions require dismissal. Like his federal claims, Relator's state law claims are riddled with flaws. They should be dismissed in their entirety alongside the federal claims or, at the very least, narrowed based on, *inter alia*, applicable statutes of limitation.

[3] This requirement pertains to any claims that pre-date the effective date of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010).

Relator's TAC is too deficient to survive—and he chose not to even try to cure the defects. The TAC should be dismissed with prejudice under Rules 8, 9(b), and 12(b).

ARGUMENT

I. NOTHING SHORT OF DISMISSAL CURES THE FIRST-TO-FILE DEFECT

Relator's action suffers from a first-to-file defect because two FCA actions alleging a materially identical scheme were pending when Relator filed his initial complaint on July 26, 2010. *See* ECF 68, Exs. 1–5. The only way to cure this defect is to dismiss this action.[4]

Relator argues that dismissal is not required because (1) *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter* ("*Carter I*"), 135 S. Ct. 1970 (2015), purportedly "teaches that the earlier-filed *Caryatid* and *Lam[p]kin* cases do not bar the TAC once they were dismissed"; (2) Relator's action is not "related" to *Caryatid* and *Lampkin* because those complaints did not allege "nationwide" misconduct; and (3) Relator cured the first-to-file defect by amending his complaint. ECF 73 at 5–7. None of his arguments is availing.

First, Relator misapprehends *Carter I*, which held only that the first-to-file bar does not preclude "new" related claims in perpetuity, which rendered improper the district court's dismissal of the claims with prejudice. 135 S. Ct. at 1973, 1979. As the district court in *Carter* recognized on remand from the Supreme Court, *Carter I* did not address whether an existing action must be dismissed without prejudice to allow for refiling after the first-filed action is no longer pending. *See Carter II*, 144 F. Supp. 3d at 876.

Second, Relator asserts that "[n]othing in either of [the two] complaints would have alerted the Government" to the purported "nationwide" scheme underlying the TAC. ECF 73 at 5–6 & n.7. But the *Lampkin* complaint specifically alleged "nationwide" misconduct. ECF 68

[4] *See, e.g.*, *Shea v. Verizon Commc'ns, Inc.*, 160 F. Supp. 3d 16, 30 (D.D.C. 2015); *United States ex rel. Carter v. Halliburton Co.* ("*Carter II*"), 144 F. Supp. 3d 869, 876–77, 883 (E.D. Va. 2015).

Ex. 3 ¶ 16 (*Lampkin* FAC) (alleging that drug samples were distributed through hundreds of free patient care kits given to doctors "nationwide on a monthly basis").

In any event, Relator's Opposition essentially concedes that the *Lampkin* and *Caryatid* complaints sufficed to alert the Government of the alleged misconduct. According to Relator, "Defendant received actual notice of the claims in this case no later than the time that the earlier actions [*Caryatid* and *Lampkin*] were unsealed in 2012." ECF 73 at 27. If those actions put Allergan on "notice," then they sufficed to alert the Government as well. This is especially true because the Government received not only the complaints, but also "disclosure of substantially all material evidence and information" supporting the complaints. *See* 31 U.S.C. § 3730(b)(2).[5]

Third, this Court should decline to follow cases that hold that supplementing or amending a complaint cures a first-to-file defect. Those cases "fail[] to adhere to the plain text of § 3730(b)(5)." *United States v. Unisys Corp.*, No. 1:14-cv-1217, 2016 WL 1367163, at *9 (E.D. Va. Apr. 5, 2016) (criticizing *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015), for "failing to adhere to the plain text of § 3730(b)(5)"). The FCA's "plain text" bars relators from "bring[ing]" a related "*action*," 31 U.S.C. § 3730(b)(5), not merely a related *complaint*; this demonstrates that "an amendment will not cure the first-to-file bar." *Carter II*, 144 F. Supp. 3d at 880; *Shea*, 160 F. Supp. 3d at 30 ("No matter how many times [Relator] amends … it will still be true that he 'br[ought] a related action based on the facts underlying the [then] pending action.'" (third alteration in original) (quoting 31 U.S.C. § 3730(b)(5))).[6]

Further, the Second Circuit has applied the first-to-file provision as a jurisdictional bar.

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[5] *See also United States ex rel. Smith v. Yale-New Haven Hosp., Inc.*, 411 F. Supp. 2d 64, 76 (D. Conn. 2005) (minor variations in details about the purported kickback types do not amount to "a different type of wrongdoing" such that they shield a complaint from the first-to-file bar).

[6] Because *Carter I* did not address whether dismissal without prejudice is proper to cure a first-to-file defect, it did not, as Relator asserts, overrule the cases on which Allergan relied.

See, e.g., *United States ex rel. Pentagen Techs. Int'l, Ltd. v. CACI Int'l Inc.*, No. 97-6326, 1999 WL 55259, at *1 (2d Cir. Feb. 5, 1999) (affirming dismissal "for lack of subject-matter jurisdiction"). Whether subject-matter jurisdiction exists "depends on the state of things at the time of the action." *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473 (2007) (citation; internal quotation marks omitted).[7] Here, the key date is the date of Relator's original complaint.

Accordingly, this Court should dismiss Relator's action because dismissal is "[t]he only way to cure this particular [first-to-file] defect." *Shea*, 160 F. Supp. 3d at 30.[8]

II. THE GOVERNMENT'S POSSESSION OF FACTS DISCLOSING THE ALLEGED FRAUD TRIGGERED THE FCA'S PUBLIC DISCLOSURE BAR

Relator attempts to rebut Allergan's public disclosure argument by asserting that the Seventh Circuit decision on which Allergan relied has been "abrogated." ECF 73 at 8. He is wrong. Neither case that Relator cites overruled or abrogated *United States v. Bank of Farmington*, in which the Seventh Circuit held that "[d]isclosure of information to a competent public official" constitutes a public disclosure. 166 F.3d 853, 861 (7th Cir. 1999).[9]

To the contrary, just this year the Seventh Circuit declined to reconsider *Bank of*

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[7] Relator asserts that the first-to-file bar is not jurisdictional. The Second Circuit and "numerous courts of appeals" have disagreed. *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 119–20 (D.C. Cir. 2015), *cert. denied*, 136 S. Ct. 2505 (2016); *see also Pentagen Techs. Int'l, Ltd.*, 1999 WL 55259, at *1.

[8] Relator worries that dismissing this action under *Shea* and *Carter II* would contravene *Carter I* because it would bar his case. ECF 73 at 5 n.6. *Shea* and *Carter II*, however, require dismissal without prejudice and both prior suits are no longer pending. Standing alone, the first-to-file bar would pose no obstacle to refiling this action.

[9] Although *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009), overruled *Bank of Farmington*'s interpretation of when an FCA suit is "based upon" a public disclosure, it left in place (and in fact relied upon) *Bank of Farmington*'s interpretation of "publicly disclosed." *Glaser*, 570 F.3d at 909–10, 913–14. Relator also relies on *dicta* from *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 559 U.S. 280 (2010). But *Graham* is inapposite. The issue there was "whether the reference [in section 3730(e)(4)] to 'administrative' reports, audits, and investigations … encompasses disclosures made in state and local sources as well as federal sources." *Id.* at 283. In observing that the touchstone was "not whether [the allegations] have landed on the desk of a DOJ lawyer," the Court was merely rebuffing the relator's argument that "administrative reports" did not include state and local reports (because, according to the relator, federal DOJ attorneys were less likely to learn of those reports). *See id.* at 299–300. The *Graham* Court did not address the issue presented here.

Farmington's public disclosure holding. *See Cause of Action v. Chi. Transit Auth.*, 815 F.3d 267, 277 (7th Cir. 2016), *cert. denied*, No. 16-131, 2016 WL 406298 (U.S. Oct. 3, 2016). There, the Seventh Circuit reiterated that information is "publicly disclosed" not only when it "is open or manifest to the public at large," but also when "the 'facts disclosing the fraud itself are in the government's possession.'" 815 F.3d at 274 (quoting *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 708 (7th Cir. 2014)).

That is precisely what happened here. Relator contends that *Lampkin* and *Caryatid* put Allergan on "actual notice" of the claims in this case. ECF 73 at 27.[10] Competent public officials—including the U.S. Attorney General and representatives of U.S. Attorney's Offices—who had those two complaints were likewise on notice of the fraud alleged here *before* Relator filed suit. *See* ECF 68 Ex. 1 at 10; ECF 68 Ex. 3 at 13. Because "the purpose of a public disclosure is to alert the responsible authority that fraud may be afoot," this Court should join the Seventh Circuit in holding that the Government's prior notice of the purported fraud "is alone sufficient to trigger the public-disclosure bar." *Cause of Action*, 815 F.3d at 275.

III. RELATOR'S FAILURE TO STATE AN AKS VIOLATION DOOMS HIS CASE

According to Relator's Opposition, Allergan "provided valuable remuneration" to physicians by: (1) distributing drug samples with the intent to induce prescriptions; (2) giving physicians care kits to provide to their patients; and (3) providing instruction sheets and prescription pads that had value as marketing tools for physicians. ECF 73 at 12–15.[11] But

[10] Relator did not "materially add[]" to those suits' allegations or satisfy the disclosure requirements; thus, he is not an "original source" such that he can avoid dismissal. *See* 31 U.S.C. § 3730(e)(4)(B); ECF 65 at 12.

[11] Relator contends that "Allergan admitted that its kickbacks had been illegal," ECF 73 at 3, and that its "activities were admittedly purposeful," *id.* at 21. *Both statements are false, as Relator's own citations demonstrate*. He bases the first specious assertion on alleged statements by Allergan personnel that the samples and patient care kits *could be misinterpreted* as kickbacks. *See id.* at 2 (quoting ECF 38 ¶ 7 (alleging that Allergan halted the care kit program because it could "be interpreted as being in violation of [the AKS]") and ECF 38 ¶ 185 (asserting that Allergan manager said that certain sampling would cease "so Allergan is not

Relator's assertions, which lack legal support and hinge on mischaracterizations of his own TAC, are unpersuasive. As his kickback theories fail, so too does his TAC.[12]

Prescription Drug Samples. Relator contends that a "closer examination of the PDMA … dooms Allergan's argument" that the PDMA permitted the promotional sampling that underlies Relator's primary AKS theory. ECF 73 at 13. Yet the Opposition is devoid of any such examination of the PDMA's text, which plainly allows distribution of samples with the "inten[t] to promote the sale of the drug." 21 U.S.C. § 353(c)(1); *see also* 21 C.F.R. § 203.3(i).[13] The PDMA's text also forecloses Relator's argument that Allergan provided too many samples. *See, e.g.*, ECF 73 at 13. Far from imposing a cap, the PDMA allows physicians to specify the quantity of samples they want. *See* 21 U.S.C. § 353(d)(2)(A)–(B) (companies may provide samples on physicians' written request, so long as the request, *inter alia*, includes "the quantity requested").

Having fled the field as to the PDMA's text, Relator instead invokes legislative intent. But the Opposition's support for Relator's misreading of the PDMA's purpose is a solitary citation to Allergan's Motion. ECF 73 at 13 (excerpting legislative history quoted by Allergan). Contrary to Relator's misapprehension of the PDMA's history, Congress intended to allow drug

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giving the appearance of engaging in any *quid pro quo*")). And, Relator quotes his own allegations as support for his second claim that Allergan "admitted[ ]" its activities were "purposeful." *See id.* at 21 (citing ECF 38 ¶¶ 2, 46–47, 127–129). To be clear, Allergan neither provided kickbacks nor did so purposefully.

[12] Without citing any authority, Relator mischaracterizes the legal defects in his TAC as "fact questions that cannot be decided" on a motion to dismiss. ECF 73 at 13. But courts *do* examine whether a plaintiff has "adequately alleged remuneration" at the motion to dismiss stage, *United States v. Medtronic, Inc.*, No. CV 11-10790, 2016 WL 2993167, at *6 (D. Mass. May 23, 2016), and dismiss actions that fail to do so, *see, e.g.*, *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1223 (W.D. Wash. 2011) (dismissing "FCA claim based on the provision of free and/or discounted procedures" because plaintiffs "failed to plausibly allege that the 'discounted' services constituted remuneration"); *United States ex rel. Dennis v. Health Mgmt. Assocs., Inc.*, No. 3:09-CV-00484, 2013 WL 146048, at *13 (M.D. Tenn. Jan. 14, 2013).

[13] Relator also claims that an Allergan compliance policy shows that the sampling violated the AKS. ECF 73 at 14 n.19. But Allergan's company policy is just that—a company policy—not the law. *See, e.g.*, *Frevert v. Ford Motor Co.*, 614 F.3d 466, 473 (8th Cir. 2010) (merely alleging "violations of Company policy" and not "a violation of a specific legal provision" "is insufficient to state a claim").

companies to provide samples so as to "encourage the written prescription of the drug." S. Rep. No. 100-303, at 2–3 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 57, 58–59. Thus, Allergan's alleged intent to "induce" prescriptions (which the PDMA permits) does not somehow convert lawful samples into prohibited remuneration.[14]

Nor can Relator explain away the OIG Guidance that the monetary value of samples is "vitiat[ed]" if a physician does not sell or bill for them. *See* 68 Fed. Reg. at 23,737–39. To be sure, Relator is right that "*if* the samples have monetary value to the recipient (e.g., a physician) … [then] the improper use of samples *may*" implicate the AKS. ECF 73 at 15 n.21 (quoting 68 Fed. Reg. at 23,739) (emphases altered). But this just begs the question. Relator never squarely addresses OIG's express statement that samples lack value to a physician unless the physician sells or bills for them.[15] And his Opposition does not claim that the TAC pleaded any such thing.

Relator's assertion that drug samples "benefitted physicians by subsidizing their out-of-pocket [surgical] costs" also is unavailing. ECF 73 at 14. Although the TAC generally discusses expenses associated with cataract surgery, ECF 38 ¶¶ 113–121, nowhere does the TAC allege that physicians would have purchased drug samples if Allergan had not distributed them. This is unsurprising; by definition, drug samples are units "not intended to be sold," 21 U.S.C. § 353(c)(1), and the PDMA bars physicians from purchasing them, *id.* § 353(c)(2) ("No person may sell, purchase, or … offer to sell [or] purchase … any drug sample."). Moreover, Relator's

[14] Because a statute's text and purpose are the touchstones for statutory analysis, *see Chen v. Major League Baseball Props., Inc.*, 798 F.3d 72, 76 (2d Cir. 2015), Relator has all but abandoned any argument that either the PDMA or the AKS forbids Allergan's alleged sampling activity. *See, e.g.*, *Greene v. United States*, 79 F.3d 1348, 1355 (2d Cir. 1996) ("When two statutes are in conflict, that statute which addresses the matter at issue in specific terms controls" absent clear intent to the contrary).

[15] *See Medtronic, Inc.*, 2016 WL 2993167, at *5 ("otherwise innocuous" free procedures were "transform[ed]" into remuneration because defendant "instructed physicians on billing Medicare for [the] procedures"); *see also United States ex rel. Freedman v. Suarez-Hoyos*, 781 F. Supp. 2d 1270, 1280–81 (M.D. Fla. 2011) (free pathology reports were remuneration because the recipient allegedly billed Medicare for them).

newfound gloss on his TAC fails to account for his allegations that the samples were ultimately provided for the benefit of patients, not physicians. *See, e.g.*, ECF 38 ¶¶ 4, 32, 47, 195 (all alleging that physicians provided the samples to their cataract patients).

Patient Care Kits. Relator's Opposition also contends that Allergan provided value to physicians by bundling samples with other items in patient care kits. As an initial matter, this argument contradicts the TAC, which alleges that the care kits' contents were of value (albeit "nominal" value) *to patients*, not physicians. ECF 38 ¶¶ 137, 153, 162.[16]

No more plausible is Relator's assertion that the display of the practice or doctor's name on the care kits provided value to physicians because the kits induced patients to select a particular physician. ECF 73 at 14–15. Yet, as Allergan's Motion explained, Relator's "advertising value" theory is illogical given that the TAC alleges that physicians only provided the kits to patients *after* they had already selected a physician to perform their surgery. *See* ECF 65 at 15–16. The value of any such advertising or marketing—to patients who are already in the fold—is nil and thus is not actionable. *See United States ex rel. Westmoreland v. Amgen*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011); *cf. Miller v. Abbott Labs.*, 648 F. App'x 555, 561 (6th Cir. 2016) (per curiam) (items must be valuable enough to reasonably induce action by recipient). Because Relator's theory that the care kits were remunerative *to physicians* is implausible, it is legally deficient. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

Instruction Sheets and Preprinted Prescription Pads. Relator's Opposition also bets heavily on allegations that were no more than afterthoughts in his TAC—specifically that

[16] This does not run afoul of the AKS. *See* OIG Guidance, 68 Fed. Reg. at 23,737 (a free product must have "independent value" to the recipient referral source to implicate the AKS).

Allergan provided "customized free" patient instruction sheets and preprinted prescription pads to physicians. ECF 73 at 15. Despite his newfound focus on these alleged "inducements," Relator fails to identify any plausible, cognizable value that these items provided to physicians.

Relator's Opposition echoes the TAC, which asserts that these items had value as "marketing tool[s]" or "advertisements," ECF 73 at 15 (citing ECF 38 ¶¶ 4, 47, 137, 139, 148–153, 165, 173–174, 192, 196), because they purportedly influenced "patients to select [specific] physicians for their cataract surgeries," ECF 38 ¶¶ 47, 165. But the Opposition ignores the TAC's allegations that physicians only provided instruction sheets to patients "[i]n conjunction with their cataract surgeries," *id.* ¶ 209, that is, *after* they had already selected a physician. As with the care kits, Relator's theory that these items had any "marketing" or "advertising" value is implausible—and thus insufficient under *Iqbal* and *Twombly*.[17]

IV. RELATOR FAILED TO PLEAD THAT ALLERGAN HAD THE REQUISITE INTENT TO VIOLATE EITHER THE AKS OR THE FCA

The TAC also should be dismissed because it fails to allege—beyond conclusory statements that do not satisfy *Iqbal*—that Allergan acted with the requisite scienter.

If "the statutory text and … court and agency guidance allow for more than one reasonable interpretation … a defendant who merely adopts one such interpretation [cannot be] a knowing or reckless violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007); *see also Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1071–72 (8th Cir. 2016) (affirming dismissal of FCA claim where plaintiff failed to show defendant's interpretation of ambiguous statute was unreasonable). As explained above, the PDMA's text neither prohibits

[17] Relator also does not dispute that the prescription pads lacked independent value to physicians because they were pre-printed "for Allergan drugs," ECF 38 ¶¶ 208, 212 (emphasis added), and thus could not be used by the physicians for any purpose other than Allergan prescriptions. *Cf.* OIG Advisory Opinion No. 12-20, 2012 WL 7148096, at *2 (Dec. 12, 2012) (explaining that computer with limited uses would not have independent value).

promotional sampling nor caps the quantity of samples a company can provide. By basing his statutory intent argument on legislative history, Relator implies that he believes the PDMA's text is ambiguous as to the permissibility of the alleged sampling. *See, e.g.*, *Lee v. Bankers Trust Co.*, 166 F.3d 540, 544 (2d Cir. 1999) ("Legislative history … may be relied upon only if the terms of the statute are ambiguous.").

Because reading the AKS and PDMA to permit the alleged sampling was not objectively unreasonable (let alone reckless or knowing (as the FCA requires) or willful (as the AKS requires)), Relator cannot, as a matter of law, plead that Allergan acted with the requisite state of mind. *See Olson*, 831 F.3d at 1071–72.

V. NEITHER RELATOR NOR THE GOVERNMENT HAS IDENTIFIED A VALID THEORY OF FALSITY

A. The "Tainted" Claim Theory of Falsity Is a Radical Departure from the Pre-ACA FCA's Text, *Escobar*, and the Common Law

According to Relator, "[i]t is well settled that [a] violation of the AKS is material to the Government's obligation to pay, and renders all ensuing claims 'false or fraudulent.'" ECF 73 at 16.[18] The Government, too, presses this "tainted" claim theory (as to pre-ACA claims). *See* ECF 78 at 1–6.[19] But far from being "well settled," this "tainted" theory of falsity has been rejected by courts in this District and elsewhere. *See, e.g.*, *United States ex rel. Arnstein v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702, 2016 WL 750720, at *20 (S.D.N.Y. Feb. 22, 2016)

[18] Bizarrely, Relator claims that Allergan has not "argue[d] that it did not commit material violations of the AKS or that the kickbacks did not influence prescribing behavior." ECF 73 at 16. This is false. *See* ECF 65 at 12–17 (detailing Relator's failure to plead a predicate AKS violation), 22 (explaining that the TAC did not allege changes to the prescribing habits of a single specific physician). Relator and the Government also conflate falsity with materiality. *See, e.g.*, ECF 73 at 16; ECF 78 at 4–6. To be sure, AKS violations might affect the Government's decision to pay, ECF 78 at 5 (quoting *United States ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 363–64 (S.D.N.Y. 2014)), but that does not address falsity (as opposed to materiality).

[19] The Government also argues, in a half-hearted footnote, that so-called tainted claims are also "factually false." ECF 78 at 5 n.4. But *Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011), held no such thing. To the contrary, it focused on legally false claims (resulting from allegedly false certifications). *See id.* at 314.

("Relators argue that any claim tainted by an illegal kickback … is *per se* a false claim…. I decline [the] invitation to manufacture a new type of false claims.").[20]

Relator cites several cases, which he claims reach the opposite conclusion. ECF 73 at 27 n.38. Yet those cases either pre-date *Escobar*'s guidance regarding the meaning of "false" and "fraudulent" under the FCA or do not actually support Relator's assertions (or both).[21]

In any event, the "tainted" claim theory cannot be squared with either *Escobar* or common-law fraud principles. Under *Escobar*, analysis of the FCA begins with the common-law meanings of "false" and "fraudulent." 136 S. Ct. at 1999 (analyzing 31 U.S.C. § 3729(a)(1)). Both modify "claims," and thus the claim must include a falsehood or misrepresentation (or omit material information) for it to be "false" or "fraudulent" under the FCA. *See id.* at 1999–2000; *see also* Rest. (2d) Torts § 525 cmt. b ("'Misrepresentation' … denote[s] not only words spoken or written but also any other *conduct that amounts to an assertion* not in accordance with the truth." (emphasis added)). Nothing in the FCA's text or the common law suggests that alleged misconduct that *does not* amount to an assertion—e.g., the purported kickbacks here—can be an actionable false or fraudulent representation (without something more).[22]

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[20] *See also United States ex rel. Barmak v. Sutter Corp.*, No. 95 CIV.7637, 2002 WL 987109, at *6 (S.D.N.Y. May 14, 2002) ("I am further unwilling to presume … that a violation of the [AKS] is *ipso facto* a violation of the FCA."); *Kellogg Brown & Root Servs., Inc. v. United States*, 728 F.3d 1348, 1367 & n.20 (Fed. Cir. 2013) (fraud in the inducement cases do not mean that "an FCA claim can be based on taint from a kickback alone").

[21] Relator misstates the holdings of several of those cases. For example, *New York ex rel. Westmoreland v. Amgen*, 652 F.3d 103 (1st Cir. 2011), does not hold that kickbacks "rendered the claims at issue false or fraudulent," *id.* at 111. The court in *Westmoreland* explicitly rejected that argument because it "stretche[d] too broadly." *Id.* For its part, the Government relies on *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943). But *Marcus* is a factual falsity case: the actual cost estimates submitted to the Government were inflated as a result of improper collusion. *See id.* at 543. In contrast, the claims allegedly submitted to the Government here were factually accurate (e.g., there are no allegations that the drug prices were inflated or products were not delivered).

[22] As *Escobar* recognized, Congress can abrogate common-law elements. 136 S. Ct. at 1999 n.2. But "absent [some] indication" that Congress has done so, *id.* at 1999, the FCA's text—read with the common law—must govern (to provide companies with fair warning as to the statute's reach). Until the ACA abrogated the common-law definition of falsity with respect to claims "resulting from" an AKS violation, those claims were not *per se* false or fraudulent under the FCA.

B. Relator's and the Government's False Certification Arguments Ignore the Details of the Certifications at Issue and Binding Precedent

They contend that claims were rendered false by express or implied "certifications submitted by the various participants in the Medicare and Medicaid programs." ECF 78 at 9; ECF 73 at 19. Neither Relator nor the Government, however, grapple with the details of the statements they cite (e.g., who spoke and what they said).

But the speaker and the specific statement matter, as both *Escobar* and the common law confirm. *See Escobar*, 136 S. Ct. at 1999 (focusing on defendants that "make[] representations in submitting a claim but omit[] [their] violations of statutory, regulatory, or contractual requirements"); *see also* Rest. (2d) Torts § 526 ("[a] misrepresentation is fraudulent *if the maker*" has certain, specified knowledge (emphasis added)).[23] This is why "a person is generally liable in common-law fraud only for fraudulent representations for which he himself is responsible." *Taylor v. Am. Chemistry Council*, 576 F.3d 16, 32–33 (1st Cir. 2009).

1. The certifications that Relator pleaded—albeit without identifying any certifiers—do not salvage Relator's case. Both Relator and the Government quote Form CMS-855I, which physicians must sign before they can bill Medicare for their services. Even setting aside that those forms pertain to physicians' services—not drugs reimbursed under Medicare Part D—that certification simply says that the signer "agree[s] to abide by the Medicare laws, regulations and program instructions that apply to [the signer]" and "understand[s] that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws." ECF 38 ¶ 80 (emphasis omitted) (quoting Form CMS-855I).

[23] *Fin. Guar. Ins. Co. v. Putnam Advisory Co.*, 783 F.3d 395, 402–03 (2d Cir. 2015) ("A claim for common law fraud … [must] (1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) *identify the speaker* … and (4) explain why the statements (or omissions) are fraudulent." (emphasis added)).

On its face, then, Form CMS-855I is both personal to the signer ("I understand") and forward-looking ("I agree to abide by").[24] Absent further details about the physicians' intent and knowledge at the time they signed, the TAC's reliance on those forms is misplaced—Relator simply has not pleaded facts sufficient to show falsity. *See United States ex rel. O'Donnell v. Countrywide Home Loans, Inc.*, 822 F.3d 650, 662 (2d Cir. 2016) (promises of future action are fraudulent only if made with contemporaneous "fraudulent intent not to perform"); *see also Soper v. Simmons Int'l, Ltd.*, 632 F. Supp. 244, 249 (S.D.N.Y. 1986).[25]

Relator and the Government rely on *Arnstein*, which rightly rejected the tainted claim theory but wrongly concluded that Form CMS-855I can "underpin an FCA" claim concerning prescription drug reimbursement. 2016 WL 750720, at *23. Taken together, *Escobar* and *O'Donnell* abrogate *Arnstein*'s conclusion that Form CMS-855I can support AKS-predicated FCA liability. Those cases underscore that a statement's speaker and knowledge are critical to the falsity analysis. At a minimum, *Escobar* and *O'Donnell* require an FCA plaintiff to plead far more than Relator's TAC if they wish to rely on a physician's statements about his or her own understanding of the law and intent to abide by it in the future.[26]

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[24] Similarly, Form CMS-1500 requires the signer to certify that the information provided is "true, accurate and complete." ECF 38 ¶ 82. Even if Relator had pleaded information about particular forms signed by particular physicians, those forms relate to the *physicians'* services (not drugs they prescribed), and Relator does not allege that the physicians misrepresented their own services. *Compare* Fact Sheet, Center for Medicare & Medicaid Services, Date Change & Phased Enforcement of Part D Prescriber Enrollment (Oct. 31, 2016) (explaining that final CMS regulation requiring physicians to enroll to prescribe drugs covered by Part D was not finalized until May 2014—and has yet to take full effect). Relator's pleading failure also dooms Relator's argument that "each claim submitted for payment after the standard Medicare Provider Agreement … incorporated the representations made in that Agreement," and thus was false. ECF 73 at 20 n.29 (emphasis omitted).

[25] According to Relator, *O'Donnell*'s holding relates only to specific intent. *See* ECF 73 at 20 n.29. Relator errs in conflating the distinct scienter and specific intent elements of common-law fraud. *O'Donnell* focused on the former element (i.e., the state of mind necessary to render an assertion fraudulent when made). The Government also fails to distinguish *O'Donnell*. *See* ECF 78 at 11. Like the contractual representations at issue there, Form CMS-855I includes certifications made *before* the alleged misconduct (not in the claims themselves).

[26] Tellingly, both Relator and the Government resort to relying on categories of certifications that the TAC never mentioned. ECF 73 at 21–23; ECF 78 at 13, 15 n.8 (offering to supplement to name "all potentially relevant

2. Relator and the Government cannot shoehorn the TAC into the* Escobar *implied certification rubric. In yet another departure from the TAC's allegations, Relator asserts that the claims "included the unique National Drug Code ("NDC") for the relevant Allergan drugs, representing Allergan's undertakings with CMS required for its drugs to be covered by Medicare and Medicaid," ECF 73 at 18–19. Relator also argues that the pharmacies' provider identification numbers "represent[ed] their prior undertakings to only submit claims that comply with all relevant laws, including the AKS," and that the pharmacies' claims "included certifications similar to CMS Form 1500." *Id.*

Relator cites no authority to support any of these boundless theories of falsity. Regardless, the inclusion of the NDCs and provider identification numbers in claims submitted by pharmacies is not akin to the "specific representations about … goods or services provided" that the *Escobar* Court discussed. 136 S. Ct. at 2001.[27] And even if it were, these theories, too, ignore the identity of the speaker, which dictates whether representations as to that individual's conduct are false or fraudulent. *See* Rest. (2d) Torts § 526 (tying analysis of whether representation is fraudulent to knowledge of the speaker). Notably, Relator's TAC pleaded that the pharmacies were "unwitting[]"—i.e., unaware of the alleged misconduct here. ECF 38 ¶ 226. And he did not plead that any particular physician knowingly made a false statement as to his or her conduct. Absent some evidence that any physicians or pharmacies misrepresented their own

certifications by participants in the Medicare and Medicaid programs"). In so doing, they reveal just how unbounded and unprincipled their certification theory is.

[27] Relator and the Government rely on *Mikes v. Straus*, but the Second Circuit's analysis of the implied certification theory there improperly conflated materiality with falsity, *see* 274 F.3d 687, 696 (2d Cir. 2001) (interpreting "false or fraudulent" to pertain to whether the Government would have paid if it knew about the misconduct). *Escobar*, however, demands an independent analysis of the two elements and, as detailed above, requires an assessment of specific representations (or omissions) by a specific speaker. 136 S. Ct. at 1999; *see also United States ex rel. Nelson v. Sanford-Brown, Ltd.*, No. 14-2506, 2016 WL 6205746, at *1 (7th Cir. Oct. 24, 2016) (relator failed to satisfy *Escobar*'s implied certification standard because he "offered no evidence that defendant … made any representations at all in connection with its claims").

compliance with applicable laws, their implied representations simply are not false or fraudulent.

VI. RELATOR RELIES ON AN IMPERMISSIBLY LENIENT RULE 9(B) STANDARD THAT THIS COURT HAS REJECTED

Although an FCA plaintiff need not plead the details of every alleged false claim, he or she must "plead the schemes with particularity *and provide representative examples of claims* submitted as a result." *United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 618 (S.D.N.Y. 2013) (Furman, J.) (emphasis added). Relator's Opposition does not (and cannot) contend that he pleaded representative examples of claims. *See generally* ECF 73 at 20–26. Because the TAC falls far short of the *Wells Fargo* standard, Relator's TAC fails.

Aware of this deficiency, Relator's Opposition lobbies for a standard that equates to the more lenient approaches rejected by this Court—in both *Wells Fargo* and a case cited by Relator—and many others. *See, e.g.*, *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 255 (S.D.N.Y. 2014) (the "reliable indicia" standard "*borders on requiring no particularity* for the 'claim' element [of an FCA allegation] *at all*" (emphases added)).[28] Relator offers no rational basis to adopt a standard here that "this Court [has] reject[ed] … as incompatible with Rule 9(b)." *Id.* Moreover, the Supreme Court's emphasis on common-law fraud principles in *Escobar* undermines the cases Relator cites, which all pre-date *Escobar*. As noted above, the Second Circuit has observed that a fraud claim must "detail the statements (or omissions) that the plaintiff contends are fraudulent [and] identify the speaker." *Putnam Advisory Co.*, 783 F.3d at 402–03 (citation and internal quotation marks omitted). Yet Relator's

[28] *See, e.g.*, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457–58 (4th Cir. 2013) ("[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government …."); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) ("pleading an actual false claim with particularity is an indispensable element" of an FCA complaint); *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (Rule 9(b) requires pleading facts "to support the allegation of *an actual false claim*," not merely detailed facts about a scheme.).

lenient standard would permit fraud plaintiffs to skip several of those elements at the pleading stage. Here, for example, Relator fails, *inter alia*, to identify any particular false or fraudulent claim or statement—let alone any particular speaker or speakers.

Even measured by a less stringent standard, the TAC is lacking. Relator's Opposition avers that the TAC "identifie[d] … specific prescriptions of Allergan drugs the doctors wrote as a result of those kickbacks; and the amounts Medicare and state Medicaid programs paid to reimburse those prescriptions." ECF 73 at 1. But the TAC belies Relator's claim:

- As an initial matter, Relator failed to plead a *single specific claim* for reimbursement submitted as the "result[ ]" of Allergan's alleged conduct. Nowhere in the TAC does Relator allege that a *single specific physician* changed his or her prescribing habits because of the alleged kickbacks. Relator cannot paper over these deficiencies by citing the TAC's conclusory assertions regarding the effects of Allergan's alleged misconduct. *See* ECF 73 at 21.[29]

- Further, Relator's assertion that he pleaded "the amounts [Government health care] programs paid for the Allergan drugs," ECF 73 at 23, is simply not true. Relator merely alleged that each physician's claims represented a "gross drug cost" of a particular amount, *see* ECF 38 ¶¶ 130–131—an amount quite different than the amount that Government *actually paid*.

- And, as Allergan's Motion explained, Relator fails to provide particulars regarding Government health care programs other than Medicare. *See* ECF 65 at 22–23.

Not surprisingly, then, the cases on which Relator relies are distinguishable. For example, in *Arnstein*, although the relators did not plead representative false claims, 2016 WL 750720, at *8, they did provide a "four-page spreadsheet" with details regarding Medicare claims and pleaded that "at least some physicians increased the number of prescriptions written for the relevant drug" in conjunction with increases in the kickbacks they received, *id.* at *7. Likewise,

[29] Relator counters that Rule 9(b)'s standard should be relaxed because "details of comparator data is [sic] in the hands of – and was specifically tracked by – Allergan itself." ECF 73 at 25. He acknowledges, however, that this lenient standard applies only where the information is "*peculiarly* within" the defendant's knowledge. *Id.* at 24 (emphasis added) (citing *Schlick v. Penn-Dixie Cement Corp.*, 507 F.2d 374, 379 (2d Cir. 1974)). Here, as Relator's TAC concedes, the Government and the States possess the relevant data, so the standard should not be relaxed. *See* ECF 38 ¶ 235 ("drug utilization data [is] submitted by plan sponsors to CMS").

in *Kester*, the Government compensated for its failure to plead specific false claims, 23 F. Supp. 3d at 265, by providing the names of pharmacies, "the approximate total reimbursement amount," and "the precise time period during which the claims were submitted," *id.*

Here, by contrast, Relator offers only sparse allegations regarding Medicare claims attributable to specific physicians. *See* ECF 38 ¶¶ 130–131. He does not name specific pharmacies that submitted the claims, much less the "precise time period[s]" or approximate reimbursement amounts. *Kester*, 23 F. Supp. 3d at 265.[30]

VII. STATUTES OF LIMITATION BAR A SIGNIFICANT PORTION OF THIS CASE

If not dismissed outright, this case should be narrowed significantly under applicable federal and state statutes of limitation. Relator wrongly asserts that the ten-year statute of repose in 31 U.S.C. § 3731(b)(2) applies. But district courts in this Circuit, as well as the majority of circuit courts that have considered the issue,[31] have held that the ten-year period "applies only to qui tam actions in which the government intervenes." *United States ex rel. Capella v. Norden Sys., Inc.*, No. 3:94-cv-2063, 2000 WL 1336487, at *12 (D. Conn. Aug. 24, 2000).[32]

Further, this Court should reject Relator's invitation to invoke Rule 15's relation-back doctrine. Where, as here, there is a first-to-file defect, courts that have declined to dismiss the

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[30] Citing *United States ex rel. Bilotta v. Novartis Pharmaceuticals Corp.*, 50 F. Supp. 3d 497 (S.D.N.Y. 2014), Relator argues that there is no basis to limit his claims' "geographic scope." ECF 73 at 25. In *Bilotta*, however, the Government "identified specific false reimbursement claims" *and* pleaded the alleged kickback scheme "with sufficient particularity." *Id.* at 521, 526 n.12. Here, Relator did neither.

[31] *See, e.g.*, *United States ex rel. Sanders v. N. Am. Bus Indus., Inc.*, 546 F.3d 288, 293 (4th Cir. 2008) ("Congress intended Section 3731(b)(2) to extend the FCA's default six-year period only in cases in which the government is a party …."); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 725 (10th Cir. 2006) ("[Section] 3731(b)(2) was not intended to apply to private qui tam relators at all.").

[32] *See also United States ex rel. Thistlethwaite v. Dowty Woodville Polymer, Ltd.*, 6 F. Supp. 2d 263, 265 & n.1 (S.D.N.Y. 1998) (reading section 3731(b)(2) to apply only to the Government most "closely adheres to the [FCA's] language," which ties the tolling provision to a U.S. official's knowledge rather than to that of a relator). The cases on which Relator relies, ECF 73 at 28 n.41, are "no longer viable in light of the Supreme Court's recent holding in … [*United States ex rel.*] *Eisenstein* [*v. City of New York*, 556 U.S. 928, 932–37 (2009)]." *United States ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 694 & n.54 (E.D. Pa. 2009).

action entirely have instead used the date of the first pleading that would survive the first-to-file bar as the operative date for the applicable limitations period. *See United States v. Cephalon, Inc.*, 159 F. Supp. 3d 550, 561–62 (E.D. Pa. 2016). Relation back in these circumstances "would circumvent the deliberate roadblocks set up by the FCA," *Makro Capital of Am. v. UBS AG*, 543 F.3d 1254, 1260 (11th Cir. 2008), by allowing Relator to claim the benefit of a filing date of a pleading that was barred when filed.[33] In sum, this Court should dismiss Relator's claims to the extent they relate to any claims submitted before May 23, 2010 (i.e., six years before the TAC).

VIII. RELATOR'S STATE LAW CLAIMS SHOULD BE DISMISSED

Relator's state law claims fall alongside his federal claims. But even if this Court permits Relator's case to proceed, his state law claims must be narrowed for several reasons:

- Relator agrees that the TAC's state law counts do not "apply to conduct that occurred prior to [each state statute's] effective date." ECF 73 at 29.
- Relator's New Mexico claim should be dismissed in its entirety because Relator had six years (and two amended pleadings) to ascertain (and then allege) that New Mexico issued him a determination of substantial evidence.[34]
- Relator also fails to allege—again despite ample time to do so—that Texas intervened or that Delaware made a substantial evidence determination.[35]

IX. RELATOR FAILS TO STATE A VIABLE RETALIATION CLAIM

"[I]nternal reporting … must allege fraud on the government" to constitute "protected activity." *McKenzie v. BellSouth Telecomm., Inc.*, 219 F.3d 508, 516 (6th Cir. 2000); *see also*

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[33] Relator cites *E.R. Squibb & Sons, Inc. v. Lloyd's & Companies*, 241 F.3d 154, 163 (2d Cir. 2001) (per curiam), in claiming that amendments to cure subject-matter jurisdiction defects relate back. But courts only apply that principle where relation back is "both equitable and not specifically barred by the statute." *Makro*, 543 F.3d at 1260 (distinguishing *Squibb* on this basis). Here, relation back would be inequitable to Allergan and would circumvent the FCA's statutory first-to-file bar.

[34] *See United States ex rel. Cestra v. Cephalon, Inc.*, No. 14-1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015) (dismissing relator's New Mexico claim with leave to amend).

[35] This also warrants dismissal of those two counts to the extent they are based on conduct preceding those states' removal of their intervention and substantial evidence requirements, respectively. The key dates are July 16, 2009, *see* Del. Code Ann. tit. 6 § 1203 (2000), and May 4, 2007, *see* Tex. Hum. Res. Code § 36.104(b) (2008).

Garcia v. Abbott House, No. 14-cv-8703, 2016 WL 796864, at *7 (S.D.N.Y. Feb. 22, 2016) (internal reporting that is unrelated to "exposing a fraud upon the government" is not activity "in furtherance of an [FCA] action") (internal quotation marks omitted).

The TAC alleges that Relator reported "concerns" about sampling, ECF 38 ¶¶ 268–269, but nowhere does it allege that Relator ever reported to Allergan any concerns regarding false claims or fraudulent activity in connection with Government payment. Relator's Opposition points to the TAC's after-the-fact assertion that the sampling involved products that "may be reimbursed" by the Government. *See* ECF 73 at 30 (citing ECF 38 ¶ 269). That is no substitute for reporting fraud. *See, e.g.*, *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 269 (W.D.N.Y. 2010) (plaintiffs did not allege reporting "Medicare/Medicaid fraud" to employer).[36] And Relator's own authority confirms as much. *Cf. Fisch v. New Heights Acad. Charter Sch.*, No. 12 Civ. 2033, 2012 WL 4049959, at *5 (S.D.N.Y. Sept. 13, 2012) (relator investigated alleged "fraudulent submissions" to the Government for payment). Thus, Relator's retaliation claim must be dismissed.

CONCLUSION

This Court gave Relator a chance to replead, and Relator instead rolled the dice with his TAC. But the TAC is too flawed—and the Relator's and the Government's legal theories too tenuous—to survive. Relator's TAC should be dismissed with prejudice.

[36] *See also Faldetta v. Lockheed Martin Corp.*, No. 98 Civ. 2614, 2000 WL 1682759, at *12 (S.D.N.Y. Nov. 9, 2000) (relator failed to allege protected activity because "it is not enough that an employee merely investigates his employer's non-compliance with federal regulations"). This would hold true even ***if*** Relator had reported any alleged AKS violations, which he does not allege. *See United States ex rel. Woods v. N. Ark. Reg'l Med. Ctr.*, No. 03-3086, 2006 WL 2583662, at *5 (W.D. Ark. Sept. 7, 2006). (As the Opposition acknowledges, the only "concerns" Relator allegedly reported related to "sampling directives and activities." ECF 73 at 29–30.)

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Respectfully submitted,

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I hereby certify that on November 2, 2016, true and correct copies of the foregoing pleading have been served on the following in the manner listed below.

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